

## GlobalSubmit COMMUNICATE



### Solution Benefits

- Refer back to record of non-submissions correspondence, such as emails and phone calls
- Sort information and apply filters to create smart views for each user role
- Display commitments by Agency or individual product
- Real-time reports based on future commitments and historical correspondence
- Visibility— anytime, anywhere access for all team members in the Secure CLOUD

### A Central System to Track Agency Correspondence and Commitments

Synchrogenix's GlobalSubmit COMMUNICATE for agency correspondence and agency commitments is a reliable, scalable system for capturing, tracking, managing, and acting upon vital regulatory information.

COMMUNICATE was designed as an improved, and realistic, user experience for regulatory professionals short on alternatives. In all likelihood, you've been left to choose between two options not closely aligned to organization goals—costly, overly complex systems or homegrown mash ups consisting of spreadsheets and documents with conflicting information.

Our solution emphasizes the end user experience while capturing all of the important information departments need to respond to Agency requests and fulfill commitments in a timely manner. Regulatory professionals can easily customize the system to fit their needs. For example, a Regulatory Affairs Manager working for a large pharmaceutical company with thousands of products globally can easily apply a filter in COMMUNICATE to display only commitments relevant to their role.

### Built for How Regulatory Professionals Really Work

Synchrogenix's GlobalSubmit Regulatory Information Management (RIM) solution was designed to help regulatory professionals in the pharmaceutical industry meet their daily obligations without wasted motion.

By offering COMMUNICATE, MANAGE, and REGISTER as standalone or integrated products, sponsors can realize a true return on investment by only utilizing functionality essential to each user role. Additional customization options such as filters allows each user to build views and create reports targeted to their individual responsibilities.

### Agency Correspondence

Synchrogenix's GlobalSubmit COMMUNICATE allows users to create accurate records of non-submissions information exchanged between sponsor and Agency—a fundamental day-to-day responsibility for regulatory professionals. Those records can then be accessed and shared throughout a product's lifecycle to inform critical development, promotional, and compliance decisions.

Featuring a user-friendly design, COMMUNICATE takes large amounts of information across many products, and potentially multiple agencies, and distills it down into smart user categories.

## Agency Commitments

GlobalSubmit COMMUNICATE is a sensible solution for tracking what commitments were made to various agencies and when those commitments are due. For example, you would track U.S. Food and Drug Administration 483 responses due resulting from an audit as commitments in the system.

Our solution simplifies entering, tracking and meeting commitments on time with complete internal transparency. The risk of having a study placed on hold, taking a manufacturing site offline or a cancelled marketing license is mitigated.

## Other RIM Product Available—Integrated Solution

GlobalSubmit MANAGE



**Submission  
Tracking**



**Regulatory Activity  
Status**

## Challenges Addressed

- Difficulty accessing and acting upon stored regulatory intelligence due to overly complex, nested hierarchies
- Unreliable DIY systems don't provide adequate visibility and reporting across regulatory teams
- Status quo RIM systems are not representative of real world user roles
- Collected regulatory data is not secure nor are its contents dependable

For more information, visit our website at [www.synchrogenix.com](http://www.synchrogenix.com) or email [contactus@synchrogenix.com](mailto:contactus@synchrogenix.com).

## Synchrogenix - Regulatory and Communications Strategy, Science, and Solutions

Synchrogenix provides regulatory and communications strategy, science, and solutions to life science companies worldwide. Our regulatory expertise and innovative technology bridges the full regulatory continuum to propel treatments to the market by meeting the needs of all stakeholders and improving public health outcomes.